



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

g1919a

October 18, 2001

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

**WARNING LETTER**  
**CHI-3-02**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Dino F. Romanucci  
Romanucci Enterprises, Inc.  
dba Belgo Pasta Products  
2820 S. Cicero Avenue  
Cicero, IL 60804

Dear Mr. Romanucci:

An inspection of your firm by the U.S. Food and Drug Administration (FDA) on August 20, 21, 23 and 28, 2001, documented numerous insanitary conditions at your facility. The inspection was conducted at the request of the U.S. Department of Agriculture, Food Sanitation and Inspection Service (FSIS), following their reported finding of similar insanitary conditions at your plant, which manufactures meat/poultry dinner entrees, as well as entrees regulated by FDA that do not contain meat or poultry. This letter refers to our findings concerning FDA-regulated products only.

The insanitary conditions observed at your firm during our inspection cause products you manufacture, store and distribute to be adulterated, within the meaning of Section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). They are adulterated because they have been, prepared, packed or held under conditions whereby they may have become contaminated with rodent and insect filth. Specifically, the inspection disclosed the following insanitary conditions:

- At least five live sightings of rats were made in the central area of your firm, where the floor has been torn up during your remodeling operation.
- Rodent fecal pellets were noted in several floor areas of your firm, including the northwest corner, the north wall area near pallets of packaging material, and along the inner wall near cast iron pipes. Pellets were also observed among unused equipment near the overhead dock door in the southwest corner of the warehouse, and in the room east of the torn-up floor area.

- Rodent-gnawed holes were observed in several parts of your plant, including in the floor in the room adjacent to the manufacturing area, and in the overhead west door. Rodent burrows were seen under concrete edges of the torn-up floor area.
- Live and dead insects (including seed chalcids) were found on the floor near the northwest door. Flies and moths were observed near the west end of the warehouse where a makeshift door has openings in it. In the same area, flies were noted in crushed tomato sauce cans.
- Structural openings, which can contribute to both rodent and insect infestations, were noted in the northwest door and the north door.
- Standing water was observed on the floor near and around several freezer units in the south part of the plant.

Our laboratory confirmed rodent fecal pellets and seed chalcids (very small wasps) in a sample collected from various areas of your plant.

At the close of the inspection, you were issued a FDA 483, Inspectional Observations, listing deficiencies observed during the inspection. (A copy of the FDA 483 is enclosed.) Our investigators reported that you have walled off and chemically treated the construction area where live rats were seen, have sealed burrows, and have cleaned up the areas in your firm that contained rodent fecal pellets. You have also discarded packaging materials and cast iron pipes from rodent-contaminated areas, and sealed rodent-gnawed holes in doors. Additionally, you have cleaned up areas that contained insects.

While we acknowledge these corrective actions, your response to insanitary conditions in the current inspection should include a specific, comprehensive approach to monitor and prevent insanitary conditions and practices from rendering your operation out-of-control.

The above-listed violations are not intended to be all-inclusive. It is your responsibility to assure adherence to each requirement of the Act and its regulations, including being vigilant that products received, manufactured, stored, and distributed in interstate commerce meet all requirements. We request that you take prompt action to correct all violations.

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Please provide this office, within 15 days of receipt of this letter, a detailed response stating the actions you plan to take, or have taken, to correct and prevent the recurrence of these objectionable conditions. Provide the time within which corrections will be completed, reasons why any corrective action cannot be completed, and documentation to show that corrections have been made. Failure to take prompt action to correct all violations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Your reply should be directed to James Karpus, Compliance Officer, at the Chicago District Office.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director

cc with enclosure: Mr. Gabrielle C. Romanucci, Vice President  
Romanucci Enterprises, Inc.  
dba Belgo Pasta Products  
2820 S. Cicero Avenue  
Cicero, IL 60804

cc with enclosure: Mr. Vincente Grande, Production Manager  
Romanucci Enterprises, Inc.  
dba Belgo Pasta Products  
2820 S. Cicero Avenue  
Cicero, IL 60804